

Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 61, 63-90 and 92-126 are pending in the application, with claims 61 and 90 being the independent claims. Entry of the foregoing amendment is respectfully requested as it merely corrects claim numbering and more clearly defines the invention without raising new grounds. Support for this amendment can be found, *inter alia*, on page 4, line 4 through page 5, line 35. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Objections to the Claims

The Examiner has objected to the claims for repeating claim number 121. The new listing of the claims has rectified this oversight, including correcting the dependencies. Applicants request that the objection be withdrawn.

Previous Rejections

Applicants thank the Examiner for withdrawing all previous rejections.

Rejections under 35 U.S.C. § 102

Claims 61, 67-69, 74-76, 81-85, 87-89, 121, and 123-124 were rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by Weyer *et al.* Specifically, the
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Examiner alleged that "Weyer *et al.* teach high throughput parallel screening method (multiple well-format) of claims 61" and goes on to allege that the specific limitations of the listed dependent claims are also taught. Applicants respectfully traverse this rejection and request that it be withdrawn.

For rejections under 35 U.S.C. § 102, the Federal Circuit held "[a] claim is anticipated only if *each and every element* as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 613, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). Applicants assert that Weyer *et al.* does not teach each and every element of the pending claims for at least the following reasons and respectfully request that the rejection be withdrawn.

Weyer *et al.* does not teach the application of a test substance to the test cells in *one operation* as required in step (b) of claim 61. Instead, Weyer *et al.* teaches a comparative screen in which the same cells with the same receptors underwent different tests, *e.g.* luciferase and binding assays utilizing A20 cells expressing the NK2 receptor. *See* page 196, beginning of second full paragraph. There is no disclosure of testing cells of the same type expressing different receptors with test agent *in one operation*. Instead, various comparisons are made from tests comprising more than one operation or multiple tests. In the Materials and Methods section, the luciferase assays are described as being performed with cells containing the NK2 *or* the 5-HT₂ receptors, but no discussion of performing the tests in one operation is presented. The only comparison of the responses between the two different receptor-containing cells is presented in the paragraph beginning on page 196. By conducting *several* experiments, the responses are measured

and compared, *not* in a single operation. Further, all data presented in Weyer *et al.* is of experiments using a single cell type.

In contrast, as mentioned previously, the instant invention requires that the test substance be applied *in one operation* to more than one test cell containing different biological target molecules. The specification states that

The concept of "parallel screening" is generally applied to the logistic mechanism in screening whereby a number of different assays or assay formats are carried out with the same arrangement of equipment under the control of a robot.

The present invention was based on the idea of further developing this approach for comparative screening, by simultaneously charging a number of different cellular assay formats from the same supply of substance.

Page 4, lines 4-13. The specification goes on to summarize

The main feature of the invention consists in the fact that the same substance is applied to a number of different cellular substrates in one operation.

Page 5, lines 29-31. The claims have been amended to more clearly recite that the test substance is applied from one supply to a more than one cellular substrate, as required by "one operation". Weyer *et al.* does not teach this crucial aspect of the present invention and thus cannot anticipate claim 61 or dependent claims 67-69, 74-76, 81-85, 87-89, 121, and 123-124. Applicants respectfully request that the rejection be withdrawn.

Rejections under 35 U.S.C. § 103

In re Vaeck (947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)), outlines the factors required for establishing a *prima facie* case for obviousness: prior art references that teach all claim limitations, a motivation to combine the teachings in the references themselves or knowledge known to a person of skill in the art at the time the invention was made, and a reasonable expectation of success from the combination of elements in the references. As discussed below, Applicants respectfully assert that these requirements have not been met to support a *prima facie* argument for obviousness for the instant claims.

A. Weyer *et al.* in view of Johnson

Claims 63, 64, 66, 70, 77-80, 90, 92, 93, 95-99, 103-114, 116-120, 122, 125, and 126 were rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over Weyer *et al.* in view of Johnson (WO 95/28421). Specifically, the Examiner asserted that the alleged screen of Weyer *et al.* combined with the target molecules and biological activities of Johnson render the claimed invention obvious. Applicants respectfully traverse this rejection.

The deficiencies of Weyer *et al.* has been discussed *supra* and remain applicable in the present rejection. Johnson does not teach the claimed high throughput screen with application of the test substance in one operation or from the same supply and thus does not overcome these deficiencies. Johnson merely characterizes the response of various second messenger protein kinases to various stimuli and putative regulatory compounds.

See page 61, line 16 to page 62, line 23. No disclosure of the high throughput screen of the claimed invention is provided. The burden of a *prima facie* case for obviousness has not been met as no combination of these references would arrive at the claimed invention. Thus, Applicants respectfully request that the rejection be withdrawn.

B. Weyer *et al.* in view of Johnson and in further view of Bischoff and Brown

Claims 65, 71-73, 94, and 100-102 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Weyer *et al.* in view of Johnson and in further view of Bischoff (U.S. Pat. No. 5,705,342) and Brown (U.S. Pat. No. 5,929,081). The Examiner asserted that in addition to the teachings of Weyer *et al.* and Johnson discussed *supra*, Bischoff allegedly teaches Bcl-2, while Brown allegedly teaches Bcl-2 and various receptors. Applicants respectfully traverse this rejection.

The deficiencies of Weyer *et al.* and Johnson has been discussed *supra* and remain applicable in the present rejection. Bischoff and Brown do not remedy these deficiencies as neither teach the claimed high throughput screen with application of the test substance in one operation or from the same supply. The burden of a *prima facie* case for obviousness has not been met as no combination of these references would arrive at the claimed invention. Thus, Applicants respectfully request that the rejection be withdrawn.

C. Weyer *et al.* in view of Chalfie

Claim 86 was rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Weyer *et al.* in view of Chalfie (U.S. Pat. No. 5,491,084). Specifically, the

Examiner asserted that the alleged screening method of Weyer *et al.* and the green fluorescent protein (GFP) of Chalfie render claim 86 obvious. Applicants respectfully traverse this rejection.

The deficiencies of Weyer *et al.* have been discussed *supra*. As discussed in Applicants' previous Reply, Chalfie merely teaches the use of GFP as a reporter gene. It does not teach the claimed high throughput parallel screen with application of the test substance in one operation or from the same supply, nor does Chalfie remedy any of the specific deficiencies of Weyer *et al.* Therefore, since this combination of references does not teach each and every element of the claims, Applicants assert that the Examiner has not met the burden for a *prima facie* case for obviousness. Applicants respectfully request that the rejection be withdrawn.

D. Weyer *et al.* in view of Johnson in further view of Chalfie

Claim 115 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Weyer *et al.* in view of Johnson and in further view of Chalfie. Specifically, the Examiner asserted that the alleged screening method of Weyer *et al.* in view of Johnson with the green fluorescent protein (GFP) of Chalfie render claim 115 obvious. Applicants respectfully traverse this rejection.

The deficiencies of Weyer *et al.* in view of Johnson have been discussed *supra*. As discussed *supra*, Chalfie merely teaches the use of GFP as a reporter gene. It does not teach the claimed high throughput parallel screen with application of the test substance in one operation or from the same supply, nor does Chalfie remedy any of the specific deficiencies of Weyer *et al.* even in view of Johnson. Therefore, since this

combination of references does not teach each and every element of the claims, Applicants assert that the Examiner has not met the burden for a *prima facie* case for obviousness. Applicants respectfully request that the rejection be withdrawn.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Victoria S. Rutherford, Ph.D.
Agent for Applicants
Registration No. 52,253

Date: August 24, 2008

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600
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